IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES ON ATTACHED EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR *DAUBERT* MOTION TO EXCLUDE OR TO LIMIT THE OPINIONS AND TESTIMONY OF TERRI A. LONGACRE, M.D.

Plaintiffs in actions listed on attached Exhibit A, pursuant to Federal Rules of Evidence 702, 403, and 104, as well as the U.S. Supreme Court decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), hereby respectfully move this Court to exclude or limit certain opinions and testimony offered by the Defendants' expert Terri A. Longacre, M.D.

INTRODUCTION

The Defendants have designated Dr. Terri Longacre as an expert pathologist in the above-referenced cases. Dr. Longacre is a surgical pathologist with a subspecialty in gynecologic pathology. Exhibit B, Expert Report of Terri A. Longacre at 1 (hereinafter "Longacre Report"). Her research focus has been primarily related to gynecological and gastrointestinal cancers with an emphasis in ovarian cancer and tumors. Exhibit C, 12/19/14 Deposition of Dr. Terri Longacre (Longacre Dep.) at 72:25-73:14. However, Dr. Longacre attempts to offer opinions that are outside her area of expertise that are inadmissible pursuant to

Federal Rule of Civil Procedure ("Rule") 702[1] and *Daubert v. Merrell Dow Pharms. Inc.*[2] Moreover, several of Dr. Longacre's opinions are not grounded in reliable principles or methods as required by *Daubert* and its progeny and must be excluded on that ground as well.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.[3] The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.[4]

ARGUMENT

Prior to her involvement in this litigation, Dr. Longacre had only microscopically analyzed six explanted mesh products throughout her entire career. Ex. C, Longacre Dep. at 45:3-8. She has never published any articles related to stress urinary incontinence, polypropylene, pelvic mesh or mesh complications and has never taught any courses or given any presentations related to polypropylene mesh. *Id.* at 73:24-75:1. Her pathology practice and research has been focused almost exclusively on gynecological and gastrointestinal cancers with an emphasis on ovarian cancer and tumors. *Id.* at 73:4-14

With limited experience regarding polypropylene mesh products, it is not surprising that Dr. Longacre has admitted that she lacks the necessary experience to offer many of the opinions

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[1] Rule 72 states that one must be qualified to proferr expert testimony by "knowledge, skill, experience, training, or education."
[2] *See Daubert*, 509 U.S. 579 (1993).
[3] *See, e.g.*, *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs the admissibility of expert testimony).
[4] *Daubert*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999)

contained within her expert report nor is it surprising that she bases her unfounded opinions on a flawed methodology. Because Dr. Dr. Longacre does not have the requisite experience and her opinions are unreliable, this Court should exclude or limit her opinions to only those that are within her area of expertise.

I. Dr. Longacre Is Not Qualified To Offer The Opinions Proffered By Her In Her Expert Report.

Dr. Longacre readily admitted during her deposition that she is not "a pelvic mesh product expert." *Id*. at 74:8-12. Elaborating on this further, Dr. Longacre testified that she is not an expert on mesh design features, including pore size, shrinkage or degradation. *Id.* at 12:4-9 (not a design expert); 13:3-9 (lightweight large pore concept); 52:17-3 (shrinkage); 83:18-20 (refusing to give opinions in prior case regarding degradation). Yet, despite this clear lack of experience, Dr. Longacre offers numerous opinions in her expert report that fall squarely within these areas – including opinions related to Ethicon's polypropylene TVT, TVT-O, TVT-Exact, TVT-Abbrevo, Prolift and Prosima, traditional procedures to treat stress urinary incontinence and pelvic organ prolapse, the risks associated with pelvic surgeries and Ethicon's TVT and pelvic organ products, including their design features and physical properties such pore sizse, shrinkage and degradation. Examples of Dr. Longacre's impermissible opinions include:

TVT Slings

1) That the TVT mesh was properly designed with adequate mesh pore sizes which stimulate only a normal, minimum to mild inflammatory response associated with healthy tissue integration creating a compliant, safe and effective product. (Ex. B, Longacre Report at p. 3, 4, 5)

2) The TVT sling, with its macroporous, monofilament, polypropylene mesh, has demonstrated long-term durability, safety and efficacy. (*Id*. at 3-4)

3) Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of stress urinary incontinence and represent the current state of the art treatment of this condition. (*Id*. at 4)

4) The FDA has stated that polypropylene is safe and effective in the treatment of stress urinary incontinence. (*Id*. at 4)

5) That because of its design features, the TVT undergoes no or only clinically insignificant shrinkage; (*Id*. at 5)

Pelvic Organ Prolapse Mesh

1) Vaginal pelvic organ prolapse mesh is associated with slightly lower rates of awareness of prolapse, reoperations for prolapse, and recurrent prolapse on examination, but slightly higher rates for reoperation due to prolapse, urinary incontinence, and mesh exposure when compared to native tissue repair. *Id*. at 8-9.

2) Pelvic pain and dyspareunia are common complaints after prolapse surgery whether by transvaginal mesh repair or other procedures. *Id*. at 9.

3) Ethicon's pelvic organ prolapse mesh contains fibers that are thinner and contain a larger pore size when compared to the mesh used in mid-urethral slings; however, the host response between these two products is identical. *Id*.

However, by her own admissions, Dr. Longacre is unqualified to offer these opinions:

A: …I am not a pelvic mesh product expert --
Q: Okay.
A: -- or focused on that in research.[5]

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Q: You're focused more on the pathology –
A: Correct.
Q: -- aspects?
A: Correct.
Q: Not so much the design features of the TVT device?
A: That's correct, yes. [6]

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Q: Are you familiar with the lightweight large pore concept in mesh surgery?
A: Yes, I –

[5] Ex. C, Longacre Dep. at 74:8-12
[6] *Id*. at 12:4-10.

> A: I am familiar with the concept but that not – again, this is not an area that I'm offering an opinion.[7]
>
> ****

Dr. Longacre similarly testified that mesh shrinkage is beyond her area of expertise: "Well, again, this is not exactly in my area of expertise…" *Id*. at 52:17-53:3.

Dr. Longacre's experience in the field of anatomical and clinical pathology does not automatically qualify her as an expert in all areas of pelvic mesh and are insufficient to pass *Daubert* muster.

As one Court has noted,

> both *Daubert* and *Kumho* make it clear that the day of the expert, who merely opines, and does so on basis of vague notions of experience, is over. Experts are now held to a level of accountability that requires factual predicates, in historical fact, or in competent evidence, which allows a factfinder to independently verify the accuracy of the expert's results. Absent such reliable verification, the expert's opinion is not admissible.

Solheim Farms, Inc. v. CHN America, LLC, 503 F.Supp.2d 1146, 1150 (D. Minn. 2007).

Opinions - like those offered by Dr. Longacre - that flow neither from background nor research, that have no independent standing and are formed only for purposes of litigation should be excluded. *Daubert*, 43 F.3d at 1317 ("*Daubert II*"); *see also* Lauzon v. Senco Prods., Inc. 270 F.3d 681, 687 (8th Cir. 2001) (citing *Daubert II*, noting impetus for opinion as a factor in considering the admissibility of expert testimony); *see also Wagner v. Hesston Corp.*, 2005 WL 1540135 (D. Minn. June 30, 2005), at *6 (attached as Exhibit D) (citing *Daubert II*, noting that expert testing conducted almost entirely within the context of litigation "increase[d] the unreliability of [the expert's] opinions").

II. Dr. Longacre's Is Not Qualified To Criticize Dr. Iakovlev.

[7] *Id*. at 13:3-9

One focus of Dr. Longacre's expert report is to criticize Dr. Iakovlev's methodology and findings. However, if the Court finds, as we believe it should, that Dr. Longacre is unqualified to discuss these topics, as set forth above, she certainly is unqualified to criticize Dr. Iakovlev's studies and findings in this field and, therefore, should be precluded from offering these criticisms at trial. Dr. Longacre has limited experience analyzing explanted polypropylene mesh devices, has never performed any research on mesh, and has never published any articles or given any presentations on mesh. Dr. Longacre admitted that she is not an expert in mesh, mesh design or the physical properties of mesh as set forth in prior sections. Thus, Dr. Longacre lacks the requisite knowledge, training and experience concerning mesh and should not be permitted to criticize Dr. Iakovlev.

III. Dr. Longacre's Opinions Are Unreliable.

To be admissible, an expert's opinions must be reliable. As this Court noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'" *Cisson v. C. R. Bard, Inc. (In re C. R. Bard, Inc.)*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013).

It is clear that Dr. Longacre fails to use any scientific method here that this Court can assess, much less a reliable one. For instance, Dr. Longacre has testified that she did not conduct any independent research and, instead, relied only on what Ethicon's lawyers provided to her. Ex. C, Longacre Dep. at 66:1-16. Even then, she failed to review everything that she was provided to her, including internal Ethicon testing and other documents concerning mesh shrinkage. Dr. Longacre's deposition demonstrates that she relies mostly, if not entirely, on her

experience as a pathologist. *Id*. at 66:13-16. When asked whether the content of Ethicon's documents would be meaningful to her opinions, she indicated that the only things relevant to her opinions as a pathologist are the pathology slides. *Id*. at 57:9-13.

Moreover, while Dr. Longacre spends considerable time opining that, for example, it is impossible for a pathologist to correlate pain to the pathological findings, this opinion is contrary to Dr. Longacre's own testimony:

> A: …And although we often don't see any obvious cause of pain when we examine histologic tissue removed from patients with pain, sometimes we do see the cause of it, and one of them would be a large nerve sitting right next to a foreign body. You would assume – or you would presume that that was probably impinging on that nerve.
>
> Q: Okay. Impinging or entrapped or –
>
> A: Or just anything. Just pushing on it will cause pain….[8]

Having no real experience with mesh, mesh design, or the physical properties of mesh – and therefore no basis to opine on these issues – Dr. Longacre somehow seeks to testify that Dr. Iakovlev is incorrect in his methods and findings. Ex. B, Longacre Report at 9-13. Even more, she seeks to do so despite the fact that she cannot provide any reasoning or any information contrary to Dr. Iakovlev's opinions. Indeed, she does not specifically reference a single publication when offering any of her opinions. This type of "no it's not" ipse dixit testimony is not helpful to the jury—because it provides no scientific basis upon which the jury could rely.[9] Neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude that there is too large of an

[8] *Id*. at 40:3-15

[9] *Ipse dixit* is defined as "[h]e himself said it; a bare, assertion resting on the authority of an individual." *See* Black's Law Dictionary 828 (6th ed. 1990); *see also Sandow-Pajewski v. Busch Entertainment Corp.*, 55 F. Supp. 2d 422, 427 (E.D.Va. 1999).

analytical gap between the data and the opinion proffered.[10] That is precisely the case here. The admissibility of Dr. Longacre's unreliable or unfounded opinions presents a serious risk of confusing the issues and misleading the jury. Accordingly, Dr. Longacre should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Longacre is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in Dr. Longacre's opinions, Ethicon cannot carry this burden and Dr. Longacre's testimony should be excluded in its entirety.

Dated: April 21, 2016

Respectfully submitted,

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[10] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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